GENERICS BULLETIN
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Generics Bulletin Explains: US Adalimumab Outlook Brightens At Mid-Point Of 2024

As PBMs Face Increasing Pressure Over Suppressing Uptake For Humira Biosimilars

by David Wallace

The latest figures on uptake for rivals to Humira in the US show adalimumab biosimilars beginning to capture significant market share from the originator, AbbVie's Humira, after an initially slow start in 2023.

Ever since biosimilar competition to Humira (adalimumab) hit the US market from the start of 2023, all eyes have been on uptake trends for off-patent rivals given that the product represented the largest loss-of-exclusivity opportunity in history, valued at roughly $17bn in terms of brand sales.

Despite the excitement around the launches – which saw Amgen compete with the first US biosimilar in January 2023, followed by numerous other competitors hitting the market from July – initial uptake for adalimumab biosimilars could best be described as a slow start, with the combined total of all biosimilars representing just 2% of the market by the end of the year. (Also see "*Generics Bulletin Explains: One Year On, US Humira Biosimilars Continue To Struggle For Share*" - Generics Bulletin, 31 Jan, 2024.)

That said, positive signs did begin to be seen in early 2024, when Samsung Bioepis' quarterly US biosimilars report suggested that the market share captured by biosimilars doubled in Q1 to 4%. (Also see "*The Comeback Begins? Positive Signs Seen For Humira Biosimilars In US*" - Generics Bulletin, 22 Apr, 2024.)

And now, the *latest quarterly report published by Samsung Bioepis* reflects Humira biosimilars

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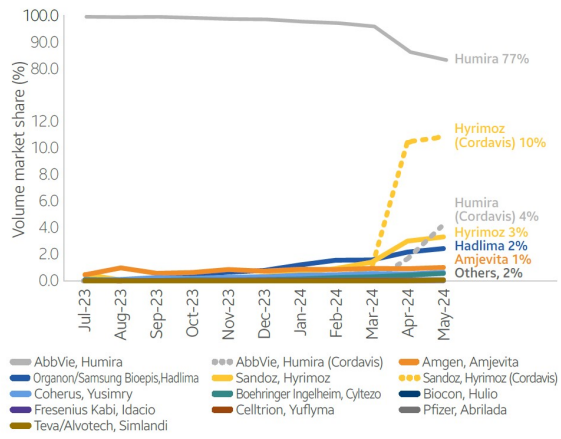


Source: Samsung Bioepis

rapidly capturing even more of the market, coming to around 18% in total as of May 2024.

The lion's share was attributable to Sandoz's Hyrimoz version that alone accounted for around 13% of the market, with the majority of this share – representing a tenth of the overall market – coming through its collaboration with CVS Health's Cordavis.

When that deal was struck, CVS revealed that its private-label version of the Sandoz product would be sold at a list price "more than 80% lower than the current list price of Humira." (Also see "*CVS Lines Up Sandoz's Adalimumab Biosimilar For US Biosimilars Subsidiary*" - Generics Bulletin, 25 Aug, 2023.)

CVS also dropped branded Humira from its major national commercial template formularies as of the second quarter of 2024, in favor of biosimilars. However, the firm also agreed a deal with originator AbbVie to provide co-branded Humira via Cordavis. (Also see "*Adalimumab Uptake Set For A Boost As CVS Drops Humira From Formularies*" - Generics Bulletin, 9 Jan, 2024.) And figures from the Samsung Bioepis report (*see chart*) show this co-branded Humira immediately capturing 4% of the market in Q2 following its launch.

"Most biosimilar gains have come from Cordavis-labeled Hyrimoz," the report summarized, also noting that "amongst the Cordavis-labeled products, Humira has 28% market share."

A Flurry Of Deals Struck By US Adalimumab Suppliers

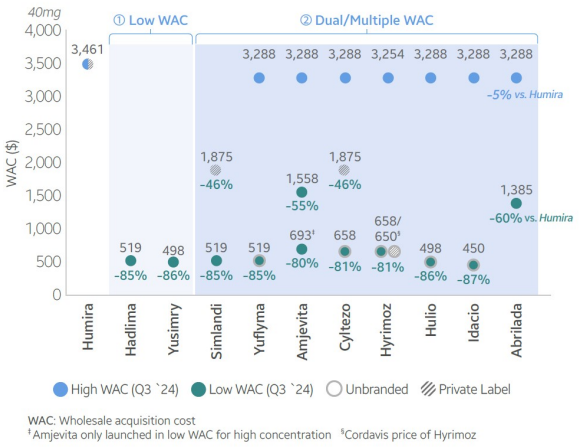
Such deals with suppliers seem to be increasingly favored by biosimilars developers as a way of capturing a significant slice of a valuable but competitive market.

In April, Cigna's Evernorth announced plans to make a Humira biosimilar available for $0 out-of-pocket for Accredo patients from June. (Also see "*Cigna Move Offers More Good News For US Humira Biosimilars*" - Generics Bulletin, 29 Apr, 2024.)

Meanwhile, the early 2024 launch by Teva and Alvotech of their long-awaited but repeatedly delayed interchangeable high-concentration 100mg/ml Humira rival, Simlandi, was accompanied by the firms revealing a private-label deal with Evernorth's Quallent Pharmaceuticals. (Also see "*Teva And Alvotech Confirm Quallent Deal On US Adalimumab*" - Generics Bulletin, 30 Apr, 2024.)

Alvotech and Teva were not the only firms to agree a deal with Quallent, as Boehringer also signed up to allow an unbranded version of its own adalimumab biosimilar to be provided via the Evernorth unit. (Also see "*Boehringer Allies With Quallent For Push On Adalimumab*" - Generics

Bulletin, 15 May, 2024.)



Samsung Bioepis

More recently, Boehringer has also provided evidence of price competition ramping up even further in the US biosimilar adalimumab market.

In July, the firm revealed a deal with GoodRx that would see it supply a version of its Humira biosimilar at an enormous 92% discount to the brand's list price. (Also see "*Boehringer Offers 92% Discount On Adalimumab Via GoodRx*" - Generics Bulletin, 24 Jul, 2024.)

This came soon after another biosimilar player, Celltrion, unveiled an offer of an unbranded version of its Humira rival at an 85% discount to the brand, adopting a dual pricing strategy in line with other suppliers that offer low list price/low rebate and high list price/high rebate alternatives to suit the desires of pharmacy benefit managers. (Also see "*Celltrion Offers 85% Discount For Adalimumab Biosimilar In US*" - Generics Bulletin, 13 May, 2024.)

More evidence of the highly competitive nature of the market came at the end of the second quarter of 2024, when Coherus Biosciences – a company that had been an early deep-discounter on adalimumab, offering upon launch last July an 85% discount (Also see "*Coherus Plots 'Lowest Price Adalimumab' With Huge Discount, Ties Up With Mark Cuban*" - Generics Bulletin, 1 Jun, 2023.) – revealed plans to check out of the biosimilar Humira market altogether.

Coherus is selling its Yusimry version of adalimumab to Meitheal Pharmaceuticals, as Coherus increasingly withdraws from biosimilars altogether. (Also see "*Coherus All But Checks Out Of Biosimilars With Meitheal Adalimumab Deal*" - Generics Bulletin, 27 Jun, 2024.)

"Biosimilar brands have provided the market with diverse wholesale acquisition cost [WAC] pricing options," the Samsung Bioepis report summarized (*see chart*). The Samsung Bioepis and Organon-partnered Hadlima and Coherus' Yusimry both offered "a low WAC of around 85%-86% less than Humira," while Boehringer's Cyltezo, Amgen's Amjevita, Sandoz's Hyrimoz, Biocon's Hulio, Fresenius Kabi's Idacio, Celltrion's Yuflyma, Pfizer's Abrilada, and Teva and Alvotech's Simlandi "offer dual/multiple pricing options (i.e. high and low WAC)."

PBMs Come Under Scrutiny

As Humira biosimilars continue to fight for market share, PBMs are increasingly coming under scrutiny due to their controlling role in the market.

The US Association for Accessible Medicines' Biosimilars Council recently recognized that "biosimilar demand grew rapidly from March to April 2024 following [CVS] Caremark formulary changes, as Hyrimoz pulled ahead in the race for adalimumab," with "the market for biosimilars…turned on its head in April 2024 as formularies shifted to cover Cordavis co-branded Hyrimoz and Humira rather than the branded reference product from AbbVie."

However, a *report from the Biosimilars Council and IQVIA* nevertheless observed that "leading PBMs continue to manipulate biosimilar competition to their own profit at the expense of patients," with PBMs continuing to "prefer the high-priced brand despite biosimilar alternatives with discounts of more than 80%."

"Further, even though a major PBM has adopted a biosimilar, its adoption still trails that of PBMs and health plans that are not dependent on rebates, and it has used the biosimilar to drive more patients into its own pharmacies and away from competitor pharmacies," the Biosimilars Council indicated.

Biosimilars Council Calls Out PBMs For Suppressing Humira Biosimilars Adoption

By Adam Zamecnik

22 Apr 2024 The US off-patent association published an analysis of IQVIA data, which highlights the role of rebate schemes that is slowing the adoption of Humira biosimilars that would save billions of dollars. *Read the full article here*

"Finally, the data reveals the extent to which PBM rebate strategies favoring the brand manufacturer helped to not only delay patient adoption of lower-price biosimilars, but also to shift patients to new, higher-priced medicines," the association said, with AbbVie having "worked to move patients to Skyrizi (risankizumab-rzaa) and Rinvoq (upadacitinib) rather than risk loss to biosimilars."

Craig Burton, executive director of the Biosimilars Council, observed that "even now, when one large, vertically integrated PBM now prefers Humira biosimilars on its commercial formulary, it is not clear that this will result in sustainable biosimilar competition over the long-term rather than being merely the latest mechanism for vertically integrated PBMs to extract value that is not then shared with patients."

Nevertheless, the Biosimilars Council said, "though organic biosimilar uptake remains low, formulary shifts have driven rapid growth for co-branded Hyrimoz and Humira." But it warned that "while some payers have adopted low-cost biosimilars, others continue to favor Humira."

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> *"Patients must have complete and easy access to lower-cost, FDA-approved biosimilars. To accomplish this, we need comprehensive reform of the PBM monopoly now."*

Recent reports from a US House of Representatives committee and from the Federal Trade Commission have also pointed the fingers at PBMs.

The FTC highlighted "rebate contracts designed to cut off access to generic and biosimilar competitors," suggesting that "agreements that exclude generics and biosimilars raise numerous concerns" (*see sidebar*), while the House committee also criticized PBMs for slowing the uptake of biosimilars. (Also see "*Another Investigation Revealing Monopolistic PBM Behavior Receives Industry's Support*" - Generics Bulletin, 30 Jul, 2024.)

US industry association the Biosimilars Forum was blunt in its assessment, stating that "the PBM monopoly stifles free market competition and forces Americans to pay more for the prescription drugs they need."

Executive director Julie Reed said PBMs were "in desperate need of reform," as they "actively block patients from being able to access lower-cost biosimilars by favoring drugs that pay the PBMs high rebates in exchange for guaranteed market share."

"This monopolistic system hurts patients by denying them access to lower-cost, safe and effective prescription drugs," Reed complained. Pointing to the FTC report's findings, she said "these unethical businesses practices should be investigated and reformed by the FTC, policymakers, and industry stakeholders."

"It is time the policymakers and industry put patients first," Reed concluded. "Patients must have complete and easy access to lower-cost, FDA-approved biosimilars. To accomplish this, we need comprehensive reform of the PBM monopoly now. Small and incremental change is not

PBMs Hinder Access To Generics And Biosimilars, Finds FTC's Investigation

By Urtė Fultinavičiūtė

12 Jul 2024

An FTC report has shown evidence of "troubling rebating practices" between pharma companies and PBMs, lowering access to generics and biosimilars. While off-patent groups commended the agency, the PBM association said the report falls short of being definitive or fact-based.

Read the full article here

enough."

"Biosimilar manufacturers are doing their part to bring lower-cost products to market. Unfortunately, PBMs have denied patients access to these lower-cost options."